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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/051,201	01/18/2002	Linus G. Fonkwe	4700-083 (04700.0467.4)	7237
30166	7590	07/01/2004	EXAMINER	
WOMBLE CARLYLE SANDRIDGE & RICE PLLC 300 N. GREENE STREET SUITE 1900 GREENSBORO, NC 27401			KRISHNAN, GANAPATHY	
			ART UNIT	PAPER NUMBER
			1623	

DATE MAILED: 07/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/051,201

Applicant(s)

FONKWE ET AL.

Examiner

Ganapathy Krishnan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-8,10-12,14-24,26-32,35-45 and 62-99 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 62-93 is/are allowed.
- 6) ☒ Claim(s) 1-3,5-8,10-12,14,15,24-32,35-37 and 94-99 is/are rejected.
- 7) ☒ Claim(s) 16-23 and 38-43 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

The amendment filed March 05, 2004 has been received, entered and carefully considered. The following information provided in the amendment affects the instant application:

1. Claims 13, 33, 34 and 46-61 have been canceled.
2. Claims 1, 16, 24 and 84 have been amended.
3. Remarks drawn to claim objection and rejections under 35 USC 103

Claims 1-3, 5-8, 10-12, 14-24, 26-32, 35-45 and 62-99 are pending in the case.

The text of those sections of Title 35, U. S. Code not included in this action can be found in a prior Office action.

Claim Objections

The objection to claim 9 is rendered moot by cancellation of the claim.

Claim Rejections - 35 USC § 103

The allowability of claims 13 and 34 in the previous office action has been withdrawn and the following rejections are made of record.

Claims 1-3, 5-8, 10-12, 14, 15, 24-32, 35-37 and 94-99 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tanner (WO 01/03677) in combination with Gilleland et al (WO 01/91721), Michaud et al (US 6143324) and Gilleland (US 6607748) of record.

Claims 1-3, 5-10, 11-12, 14, 15, 24-32, 35-37 and 94-99 are drawn to film forming compositions comprising specific percentages/percent ranges of iota carrageenan, kappa

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carrageenan, bulking agent, water and plasticizer, wherein the plasticizer is sorbitol and the bulking agent is modified starch.

Tanner et al drawn to film forming compositions, teach compositions comprising kappa/iota carrageenans, water, modified starch, and glycerin (plasticizer). Kappa carrageenan is present in the range 1 to 5.56%; iota carrageenan is present in the range 5 to 9%; water in the range 46.5 to 80%, starch (pure cote B) is 27.3% and glycerol is present in 15 and 8.3%.

Gilleland et al drawn to film forming compositions teach formulations having starch (used as a thickener), kappa carrageenan, sorbitol (plasticizer) and water (example 8, page 11) and another composition wherein the ratio of kappa and iota carrageenan is 50:50 (example 10, page 13). This combination produces a film which is stronger. Gilleland also states that a mixture of iota and kappa carrageenan should make the films easier to handle and easier seal and that blending kappa with iota carrageenan allows for higher solids while maintaining manageable viscosity. The compositions of the invention are formed by combining the dry solids, slurring in water and then heating the mixture and forming ribbons (films) and then forming coating or a capsule shell (see page 6, lines 9-25)

However, Tanner and Gilleland do not mention that starch used in their compositions is for bulking purposes.

Michaud et al et al drawn to use of starch in capsules, discloses that fillers can also act as bulking agents and in many cases this may be done using a binder and that starch is used for this purpose (col. 2, lines 8-33).

Lenaerts et al teach that starch has many uses and can act as a diluent, filler, carrier, binder, disintegrant, coating and thickener (col. 1, lines 55-60).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a film forming composition using a mixture of iota and kappa carrageenan and starch/modified starch as a bulking agent since the ingredients and their functions are seen to be disclosed in the prior art. One of ordinary skill in the art also knows that esterified starch is modified starch. Hence substituting esterified starch reads on modified starch as instantly claimed. It is also well within the purview of one of ordinary skill in the art to adjust the ratio of the bulking agent and the kappa and iota carrageenans in order to optimize the characteristics of the films produced using the same.

One of ordinary skill in the art would be motivated to do so since Gilleland's teaching shows that a mixture comprising 1:1 kappa and iota carrageenan, starch, sorbitol and water gives a film which is strong and easy to handle and seal and also has a manageable viscosity. Hence optimizing the ratio of the ingredients would give a composition that would be ideal for use in making capsule shells.

Response to Applicants' Arguments

Applicants argue that the instant composition does not teach or suggest compositions comprising kappa carrageenan in an amount less than 100% by weight of the iota carrageenan in combination with other components claimed.

Tanner et al teach compositions comprising kappa/iota carrageenan, water, modified starch (esterified starch is seen to come under the definition of modified starch since the claim 1 does not define how the starch is modified). The range of kappa carrageenan present in Tanner's composition (1 to 5.56%) and iota carrageenan (5 to 9%) is seen to read on the

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limitation "kappa carrageenan in an amount less than 100% by weight of the iota carrageenan".

This teaching in combination with the teachings of the other prior art cited above is seen to fairly suggest the compositions as instantly claimed.

Conclusion

1. Claims 1-3, 5-8, 10-12, 14, 15, 24-32, 35-37 and 94-99 are rejected.

2. Claims 16-23 and 38-43 drawn to compositions with a specified viscosity range, moisture content and tensile strength are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

3. Claims 62-93 which are drawn to a method of preparing the compositions is allowable since the prior art of record does not teach or render obvious the specific order in which the ingredients are mixed and heated to form the said composition.

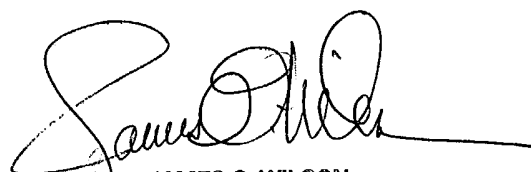
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 571-272-0654. The examiner can normally be reached on 8.30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

GK



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